DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 9, 2015

Merete Medical GmbH
% Mr. Rüdiger Hilken
Merete Medical, Incorporated
4 Crotty Lane, Suite 118, New York International Plaza
New Windsor, New York 12553

Re: K142451
Trade/Device Name: OsteoBridge™ IDSF - Intramedullary Diaphyseal Segmental Defect Fixation Rod System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: January 6, 2015
Received: January 13, 2015

Dear Mr. Hilken:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use Statement

Indications for Use

510(k) Number (if known): K142451

Device Name: OsteoBridge™ IDSF - Intramedullary Diaphyseal Segmental Defect Fixation Rod System

Indications for Use:
The device is intended to be used in the management of segmental diaphyseal bone loss of the femur in oncology patients secondary to radical bone loss and/or resection due to tumors. The intramedullary rods can be fixed with interlocking screws without or with bone cement.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

_____
Concurrence of CDRH, Office of Device Evaluation (ODE)

2. 510(k) Summary of Safety and Effectiveness Information

Date Prepared: August 2014

Submitted by:
Merete Medical GmbH
Alt-Lankwitz 102
12247 Berlin, Germany

FDA Registration Number: 3002949614

Contact Person:
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New York International Plaza
New Windsor, NY 12553
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Device Name: OsteoBridge™ IDSF - Intramedullary Diaphyseal Segmental Defect Fixation Rod System

Common Name: Intramedullary Fixation System

Classification Names: Intramedullary fixation rod
(21 CFR 888.3020)

Product Code: HSB

Proposed Regulatory Class: Class II

Predicate Devices:
K051965 – OsteoBridge™ IDSF Intramedullary Diaphyseal Segmental Defect Fixation System
K113303 – OsteoBridge™ IDSF Intramedullary Diaphyseal Segmental Defect Fixation System

Device Description:
The OsteoBridge™ IDSF - Intramedullary Diaphyseal Segmental Defect Fixation Rod System is a series of modular intramedullary rod segments that may be used as either proximal or distal segments. The segments are designed to be attached together to form a complete intramedullary rod using semicircular hollow attachment shells that are clamped together with multiple screws to create a complete intramedullary rod. The complete unit is designed to accept interlocking bone screws for additional rotational stability.
The implants from this submission are an extension of the OsteoBridge™ IDSF - Intramedullary Diaphyseal Segmental Defect Fixation Rod System (K051965/K113303). The components from this submission can be used in combination with the rod segments from the OsteoBridge™ IDSF diameter 10 to 16 mm (K051965) as well as with the dia. 5 mm interlocking screws. In addition sterile intramedullary rod segments are available in diameters of 18 mm

and 20 mm in lengths of 90 mm and 110 mm. The hollow central attachment shell for use in the femur has a diameter of 34 mm and is available in four lengths 40 mm, 50 mm, 60 mm and 70 mm with reducing bushings to allow the use of different diameter rods proximally and distally to better fit the medullary canal. If the defect size is larger than 70 mm, two attachment shells can be connected by a spacer connector.
All components of the OsteoBridge™ IDSF system are manufactured from Ti-6Al-4V titanium alloy conforming to ASTM F 136-13.

Indications for Use
The device is intended to be used in the management of segmental diaphyseal bone loss of the femur in oncology patients secondary to radical bone loss and/or resection due to tumors. The intramedullary rods can be fixed with interlocking screws without or with bone cement.

Substantial Equivalence:
The OsteoBridge™ IDSF System is technologically equivalent to the predicate devices.

Legally marketed Devices to which substantial Equivalence is claimed
K051965 - OsteoBridge™ IDSF Intramedullary Diaphyseal Segmental Defect Fixation System
K113303 – OsteoBridge™ IDSF Intramedullary Diaphyseal Segmental Defect Fixation System

Non-Clinical Performance Data:
In order to demonstrate that the OsteoBridge™ IDSF has the mechanical properties necessary to perform its intended use, and that the device performs as well as or better than the predicate device, Merete has conducted mechanical and functional testing (according to ASTM F-1264-03). The tests represent the worst case scenario for the strength of the system. All products have successfully passed all tests. The OsteoBridge™ IDSF system has hereby been proven to be mechanically safe.